Recall Alert

An update on the Cyclospora outbreak available here (https://www.fda.gov/food/outbreaks-foodborne-illness/investigation-5-state-outbreak-cyclosporiasis-cases-tied-fresh-cilantro-2026)

WARNING LETTER

Almon Healthcare Private Limited

MARCS-CMS 729291 — JULY 13, 2026

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

Delivery Method:

Via Email Return Receipt Requested

Reference #:

320-26-102

Product:

Drugs

Recipient:

Mr. Rajesh Gandhi

Chairman

Almon Healthcare Private Limited

Plot No 4, Sankalp Industrial Estate, Behind Kerala GIDC, Bavala

Ahmedabad 382240 Gujarat

India

Issuing Office:

Center for Drug Evaluation and Research (CDER)

United States

Warning Letter 320-26-102

July 13, 2026

Dear Mr. Gandhi:

The United States Food and Drug Administration (FDA) inspected your drug manufacturing facility, Almon Healthcare Private Limited, FEI 3030509366, at Plot No 4, Sankalp Industrial Estate, Behind Kerala GIDC, Bavala, Ahmedabad, from February 9 to 13, 2026.

This warning letter summarizes significant deviations from Current Good Manufacturing Practice (CGMP) for active pharmaceutical ingredients (APIs).

Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your APIs are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B).

We reviewed your March 6, 2026, response to our Form FDA 483 in detail and acknowledge receipt of your subsequent correspondence.

During our inspection, our investigator observed specific deviations including, but not limited to, the following.

1. Failure of your quality unit to exercise its responsibility to ensure the API and intermediates manufactured at your facility are in compliance with CGMP.

Your quality unit (QU) failed to perform identity testing on incoming raw materials used in the manufacture of APIs **(b)(4)**, which are intended for use in pharmacy compounding.

Specifically, your firm intentionally accepted lots of **(b)(4)** that were deliberately mislabeled by your supplier as **(b)(4)**. During the inspection, your QU admitted that this was a deliberate and ongoing practice since 2024 to circumvent your firm's lack of a required **(b)(4)** license. You subsequently used this mislabeled and untested material to manufacture multiple batches of **(b)(4)** that you ultimately shipped to the United States. Furthermore, your QU relied on your supplier's certificate of analysis without conducting supplier qualification as your standard operating procedure requires.

In your response, you acknowledge the mislabeling practice, state you have since obtained the required **(b)(4)** license, and commit to performing identity testing of all future lots of **(b)(4)**. You also state that a retrospective reevaluation of residual solvent chromatographic data confirms that peaks previously observed in the affected **(b)(4)** batches are attributable to **(b)(4)**.

Your response is inadequate. Your analytical conclusions are unsubstantiated because your response does not provide the supporting chromatograms or results from your identity tests. Furthermore, you do not provide a risk assessment for batches already distributed to the United States. Your response also does not address the systemic quality failure that allowed your firm to knowingly accept and recode mislabeled materials without performing identity testing. Finally, you fail to propose any substantive corrective actions to remediate your supplier qualification program to prevent a recurrence of this critical failure.

Without adequate testing, you do not have scientific evidence that incoming materials conform to appropriate specifications prior to use in the manufacture of your drugs. As a manufacturer, you have a responsibility to sample, test, and examine incoming materials before use in production to assure adequate quality. Executive management should immediately and comprehensively assess your company's global manufacturing operations to ensure that your systems, processes, and products conform to FDA requirements.

Your practice of receiving **(b)(4)** mislabeled as **(b)(4)** poses a significant safety risk to personnel who may handle the material without knowing its true identity. Due to lack of awareness, workers may fail to take the precautions necessary to prevent exposure. **(b)(4)** is acutely toxic to humans and has caused fatal poisoning incidents worldwide.

Furthermore, an adequate QU overseeing all elements of CGMP is necessary to consistently ensure drug quality. FDA considers the expectations outlined in ICH Q7 when determining whether API are manufactured in conformance with CGMP, including the sections on quality oversight. See FDA's guidance document Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients for guidance regarding CGMP for the manufacture of API at https://www.fda.gov/media/71518/download.

In response to this letter, provide:

- A comprehensive assessment and remediation plan to ensure your QU is given the authority and resources to effectively function. The assessment should also include, but not be limited to:
  o A determination of whether procedures used by your firm are robust and appropriate
  o Provisions for QU oversight throughout your operations to evaluate adherence to appropriate practices
  o A complete and final review of each batch and its related information before the QU disposition decision
  o Oversight and approval of investigations and discharging of all other QU duties to ensure identity, strength, quality, and purity of all products
  o Also describe how top management supports quality assurance and reliable operations including, but not limited to timely provision of resources to proactively address emerging manufacturing/quality issues and to assure a continuing state of control.

2. Failure to ensure that all test procedures are scientifically sound and appropriate to ensure that your intermediate and API conform to established standards of quality and purity.

Your firm failed to validate or adequately verify multiple test methods used for testing key starting materials and finished APIs. Specifically, you did not validate the in-house analytical methods, including the stability-indicating methods, used to support the **(b)(4)** retest dates for your products shipped to the United States. Furthermore, your firm failed to adequately implement and verify an analytical method transferred from your contract testing laboratory CTL) used for routine testing and stability studies of **(b)(4)**. Your implemented method was unable to detect multiple unknown impurities that your CTL's validated method identified.

In your response, you commit to executing forced degradation studies to demonstrate your methods are stability-indicating and to reassessing the validity of the assigned **(b)(4)** retest dates for the APIs shipped to the United States. You also commit to executing validation and verification protocols for compendial and in-house methods. You attribute the discrepancy in impurity detection in **(b)(4)** to an incorrectly set processing threshold and provide reprocessed data to suggest your results are now comparable.

Your response is inadequate because it fails to comprehensively assess your laboratory systems to ensure that all test methods are appropriately validated or verified. You have not established any interim controls for ongoing production while you conduct your retrospective review of batches tested with unvalidated methods. Additionally, while you attempt to explain the threshold differences between the CTL and the in-house verification study for **(b)(4)**, you fail to address whether the methods are truly equivalent.

Without an appropriate laboratory and stability-indicating methods, you lack adequate scientific evidence to support whether your drug products meet established specifications and retain their quality attributes through their labeled expiry.

In response to this letter, provide:

- A comprehensive independent assessment of your laboratory practices, procedures, methods, equipment, documentation, and analyst competencies. Based on this review, provide a detailed plan to remediate and evaluate the effectiveness of your laboratory system.
- A list of validated/verified chemical specifications, including test methods, used to analyze each batch of your drug products before a lot disposition decision.
  o An action plan and timelines for conducting full chemical testing of retain samples to determine the quality of all batches of drug product distributed to the United States that are within expiry as of the date of this letter.
  o A summary of all results obtained from testing retain samples from each batch. If such testing reveals substandard quality drug products, take rapid corrective actions, such as notifying customers and product recalls.
- A comprehensive assessment and corrective action and preventive action plan to ensure the adequacy of your stability program. Your remediated program should include, but not be limited to:
  o Stability-indicating methods
  o Stability studies for each drug product in its marketed container-closure system before distribution is permitted
  o An ongoing program in which representative batches of each product are added each year to the program to determine the shelf-life claim remains valid
  o Detailed definition of the specific attributes to be tested at each station (timepoint)
  o All procedures that describe these and other elements of your remediated stability program
- Confirm the retest dates for **(b)(4)** using the revalidated stability-indicating method. This reassessment should ensure that all previously assigned retest dates are accurate.

3. Failure to clean equipment to prevent contamination or carry-over of a material that would alter the quality of the intermediates and API beyond the official or other established specifications.

Your firm failed to adequately clean and maintain non-dedicated API manufacturing equipment used to manufacture as many as **(b)(4)** different APIs. For example, our investigator observed **(b)(4)** and **(b)(4)** particles on product contact surfaces, including the lid and **(b)(4)** of **(b)(4)**, and **(b)(4)** liquid draining from the **(b)(4)** even though the **(b)(4)** was

documented as “empty and cleaned.” Additionally, your firm failed to maintain cleaning records for a non-dedicated **(b)(4)** product transfer pipe.

Your cleaning verification report for **(b)(4)** addressed only batch-to-batch cleaning. It did not address product changeover. It also lacked scientific justification for product selection and residue limit calculations based on solubility, difficulty of cleaning, and toxicity, as required by your cleaning validation procedure. Your firm affirmed to our investigator that no formal cleaning validation has been performed and that you have not established a maximum allowable carryover limit as required by your procedure.

In your response, you attribute the observed residues on the **(b)(4)** to the previous batch of the same non-U.S. API, explaining that only a “gross cleaning” is performed between batches during a **(b)(4)**. You conclude there was no risk of carryover. You assert that the **(b)(4)** transfer pipe is dedicated to a **(b)(4)** and also conclude there is no cross-contamination risk and confirm you do not use cleaning logs.

Furthermore, you state that you “executed cleaning validation/verification activities for selected products” manufactured on shared equipment.

Your response is inadequate because it does not provide assurance that your cleaning processes are adequate to prevent cross-contamination and carryover risks. It addresses only the **(b)(4)** particles observed in the **(b)(4)**, attributing them to a non-U.S. API campaign, while failing to test the observed **(b)(4)** liquid and other particle deposits. You did not expand your investigation to other equipment or conduct a retrospective review of released batches to assess product impact.

Your claim that the **(b)(4)** transfer pipe is dedicated to a **(b)(4)** is unsubstantiated and contradicts information provided during the inspection. Further, you do not explain why cleaning validation was limited to selected products, nor do you provide supporting documentation to support or demonstrate that your cleaning practices adequately remove product residues.

Inadequately cleaned and maintained manufacturing equipment can lead to potential cross-contamination that could compromise your API’s quality and safety.

In response to this letter, provide:

- A comprehensive, independent retrospective assessment of your cleaning effectiveness to evaluate the scope of cross-contamination hazards. Include the identity of residues, other manufacturing equipment that may have been improperly cleaned, and an assessment of whether cross-contaminated products may have been released for distribution. The assessment should identify any inadequacies of cleaning procedures and practices and encompass each piece of manufacturing equipment used to manufacture intermediates and API products.
- Appropriate improvements to your cleaning validation program with special emphasis on incorporating conditions identified as worst case in your API manufacturing operations. This should include but not be limited to identification and evaluation of all worst-case:
  o Drugs with higher toxicities
  o Drugs with higher potencies
  o Drugs with lower solubility in their cleaning solvents
  o Drugs with characteristics that make them difficult to clean
  o Swabbing locations for areas that are most difficult to clean
  o Maximum hold times before cleaning
- A summary of updated standard operating procedures that ensure an appropriate program is in place for verification and validation of cleaning procedures for products, processes, and equipment.

CGMP Consultant Recommended

Based upon the nature of the deviations we identified at your firm, you should engage a consultant qualified to evaluate your operations and to assist your firm in meeting CGMP requirements. The qualified consultant should also perform a comprehensive six-system audit of your entire operation for CGMP compliance and evaluate the completion and efficacy of your corrective actions and preventive actions before you pursue resolution of your firm’s compliance status with FDA.

Your use of a consultant does not relieve your firm's obligation to comply with CGMP. Your firm's executive management remains responsible for resolving all deficiencies and systemic flaws to ensure ongoing CGMP compliance.

Conclusion

The deviations cited in this letter are not intended to be an all-inclusive list of deviations that exist at your facility. You are responsible for investigating and determining the causes of any deviations and for preventing their recurrence or the occurrence of other deviations.

FDA placed all drugs and drug products offered for import into the United States from your firm on Import Alert 66-40 on June 9, 2026.

Correct any deviations promptly. FDA may withhold approval of new applications or supplements listing your firm as a manufacturer until any deviations are completely addressed and we confirm your compliance with CGMP. We may re-inspect to verify that you have completed corrective actions to any deviations.

Failure to address any deviations may also result in the FDA continuing to refuse admission of articles manufactured at Almon Healthcare Private Limited located at Plot No 4, Sankalp Industrial Estate, Behind Kerala GIDC, Bavala, Ahmedabad, into the United States under section 801(a)(3) of the FD&C Act, 21 U.S.C. 381(a)(3). Articles under this authority that appear to be adulterated may be detained or refused admission, in that the methods and controls used in their manufacture do not appear to conform to CGMP within the meaning of section 501(a)(2)(B) of the FD&C Act, 21 U.S.C. 351(a)(2)(B).

This letter notifies you of our findings and provides you an opportunity to address the above deficiencies. After you receive this letter, respond to this office in writing within 15 working days. Specify what you have done to address any deviations and to prevent their recurrence. In response to this letter, you may provide additional information for our consideration as we continue to assess your activities and practices. If you cannot complete corrective actions within 15 working days, state your reasons for delay and your schedule for completion.

Send your electronic reply to CDER-OC-OMQ-Communications@fda.hhs.gov. Identify your response with FEI 3030509366 and ATTN: Jamie Dion.

Sincerely,
/S/

Francis Godwin
Director
Office of Manufacturing Quality
Office of Compliance
Center for Drug Evaluation and Research